



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

DeRoyal Industries Incorporated  
Ms. Elizabeth Wheeler  
Senior Regulatory Affairs Specialist  
200 DeBusk Lane  
Powell, Tennessee 37849

July 23, 2015

Re: K142962  
Trade/Device Name: PROTOCOL™ Incision Dressing  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: May 8, 2015  
Received: June 16, 2015

Dear Ms. Wheeler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

**Joshua C. Nipper -S**

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.  
Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K142962

Device Name

PROTOCOL(TM) Incision Dressing

Indications for Use (Describe)

For use following surgery in sutured or stapled wounds, to be used as a closed incisional wound dressing with attached packing gauze strips.

Type of Use (Select one or both, as applicable)

☒ Prescription Use (Part 21 CFR 801 Subpart D)

☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

### FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**Corporate**

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[www.deroyal.com](http://www.deroyal.com)

DeRoyal Industries, Inc.  
Traditional 510(K) Submission – PROTOCOL™ Incision Dressing  
October 10, 2014

**510(k) Summary**

**Date prepared:** October 10, 2014  
Revised May 8, 2015

**510(k) Owner:** DeRoyal Industries, Inc.  
200 DeBusk Lane  
Powell, TN 37849  
Owner/Operator #1044833

**510(k) Contact:** Elizabeth Wheeler  
Senior Regulatory Affairs Specialist  
865-362-2333  
[ewheeler@deroyal.com](mailto:ewheeler@deroyal.com)

**Manufacturer:** DeRoyal Industries, Inc.  
164 Giles Hollow Road  
Rose Hill, VA 24281  
FDA Registration Number: 1123071

**Trade Name:** PROTOCOL™ Incision Dressing

**Common Name:** Incision Dressing

**Classification:** Dressing, Wound, Drug

**Device Product Code:** FRO

**Substantial Equivalency:** DeRoyal Industries, Inc.  
Calgitrol AG Silver Alginate Foam and  
Gel Foam Dressings with or without  
Maltodextrin – K011618  
  
Covidien  
Kendall Kerlix Antimicrobial Gauze –  
K990530

**Indications for Use:**

For use following surgery in sutured or stapled wounds, to be used as a closed incisional wound dressing with attached packing gauze strips.

**Device Description:**

PROTOCOL™ Incision Dressing is a sterile, single use device. It is manufactured by using the already cleared Calgitrol AG Silver Alginate Foam and Gel Foam Dressings with or without Maltodextrin (K011618) and sewing the Kendall Kerlix Antimicrobial Gauze (K990530) to the middle of the silver dressing as an additional absorption feature. The antimicrobial gauze packing strips will be inserted in to the wound, while the silver dressing will be the primary dressing on top of the wound. Adhesive tape will be applied to hold PROTOCOL™ Incision Dressing in place.



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**Summary of Technological Characteristics:**

<b>Feature</b>	<b><u>Predicate Device</u> DeRoyal- Calgitrol AG Silver Alginate Foam and Gel Foam Dressings with or without Maltodextrin K011618</b>	<b><u>Predicate Device</u> Covidien- Kendall Kerlix Antimicrobial Gauze K990530</b>	<b><u>Proposed Device</u> PROTOCOL™ Incision Dressing</b>
Absorbency	Highly absorbent	Highly absorbent	Same as predicate
Materials	Gauze with silver alginate	Gauze with polyhexamethylene biguanide hydrochloride	Combination of predicate device materials
Design	Primary dressing	Packing gauze	Primary dressing with packing gauze

**Basis for Substantial Equivalence:**

In order to demonstrate substantial equivalence, DeRoyal evaluated the indications for use, materials, and product specifications. Testing has been successfully completed and documented to demonstrate that the proposed device is substantially equivalent to the previously cleared Calgitrol AG Silver Alginate Foam and Gel Foam Dressings with or without Maltodextrin (K011618) and Kendall Kerlix Antimicrobial Gauze (K990530). The proposed device does not raise any new issues of safety and effectiveness, and performs as well as the predicate devices.

**Clinical Studies:**

Clinical Testing was not performed for this device as it is not a high risk, class III device for which clinical evaluations are needed.

**Summary of Testing Performed:**

Pull testing was performed on the PROTOCOL™ Incision Dressing and can be found in section 018\_Performance Validation - Bench.